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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,809	06/27/2003	Leonard Katz	300622004810	6321
82359 7590 06/11/2009 Bristol-Myers Squibb Company c/o MoFo 12531 High Bluff Drive, Ste. 100 San Diego, CA 92130				
EXAMINER ROBINSON, HOPE A				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
06/11/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,809

Applicant(s)

KATZ ET AL.

Examiner

HOPE A. ROBINSON

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 7-9 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 7-9 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. The amendment filed on March 12, 2009 in response to the Office Action mailed on November 12, 2008 has been received and entered.

Claim Disposition

2. Claims 2, 7-9 and 17-19 are pending and are under examination.

Maintained-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 2, 7-9 and 17-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by Reeves et al. (U.S. Patent No. 6,759,536, October 2, 1998).

Reeves et al. teach the use of vectors and host cells in a method that produces polyketide structures. Reeves et al. teach a loading module responsible for binding the

first building block used to synthesize the polyketide and transferring it to the first extender module. Reeves et al. teach that the loading module of a DEBS consists of an acyltransferase (AT) domain and an acyl carrier protein (ACP) domain. Reeves et al. also teach another type of loading module that utilizes an inactivated ketosynthase (KS) domain an AT and ACP domains. This inactivated KS is called KS^Q, where the superscript letter is the abbreviation for the amino acid, glutamine, that is present instead of the active site cysteine required for ketosynthase activity. In addition, Reeves et al. teach that other PKS enzyme, including the FK-506 PKS, the loading module incorporate an unusual starter unit and is composed of a CoA ligase like activity domain. Reeves et al. further teach that the loading module recognizes a particular acyl-CoA (usually acetyl or propionyl but sometimes butyryl or other acyl-CoA) and transfers it as a thiol ester to the ACP of the loading module (see paragraph 10). At paragraph (6) Reeves et al. teach fkbS (a crotonyl-CoA reductase involved in the biosynthesis of ethylmalonyl CoA) from the organism *Streptomyces*. Reeves et al. teach an acyl transferase domain specific for ethylmalonyl CoA. At paragraphs 54 and 56, Reeves et al. exemplifies multiple extenders. Paragraph 100 discloses a *Sacharopolyspora*. Paragraphs 153 and 155 disclose the use of *E. coli*. Therefore the limitations of the claims are met by the reference.

Response to Arguments

4 The response filed has been considered in full. Note that the rejection of record under 35 USC 102 remains. Applicants provide mere arguments and do not specifically point out how the reference is deficient. Applicant on page 4 of the response opines that the claims have been amended to more clearly define the invention. It is noted that claim 2 is amended to delete "*Streptomyces coelicolor* (ccr)". However, no other amendments appear in the claims. The cited reference teaches the use of *Streptomyces* and the species *caelestis*, *venezuelae*, *lividans*, *coelicolor hygroscopicus* and *fradiae*. Moreover, the reference discloses crotonyl-CoA reductase involved in the biosynthesis of ethylmalonyl CoA (paragraphs 6 and 161), a loading module, KSQ domain, ACP domain, six extender modules as set forth above in the rejection. Thus, the rejection remains and applicant's statements that all limitations are not taught by the reference is incorrect.

Conclusion

5 No claims are allowable.

6. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed, Ph. D., can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652

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